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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA,

SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.

Plaintiff and Counterclaim-Defendant,

vs.

NATERA, INC.

Defendant and Counterclaim-Plaintiff.

CASE NO. 3:21-CV-04062-EMC

NATERA, INC'S EMERGENCY MOTION PURSUANT TO FED. R. CIV. P. 37(C) FOR LESSER SANCTIONS AND/OR FOR CLARIFICATION

REDACTED FOR PUBLIC FILING

Hearing: November 4, 2024
Time: 8:30 a.m.
Place: Courtroom 5, 17th Floor
Judge: Hon. Edward M. Chen

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on November 4, 2024 at 8:30 am or as soon thereafter as the matter may be heard in the court room of the Honorable Edward M. Chen, Courtroom 5 on the 17th floor of the San Francisco Courthouse located at 450 Golden Gate Avenue, San Francisco, CA 94102, Defendant and Counterclaim Plaintiff Natera Inc. ("Natera") will and hereby does move for an order of lesser sanctions pursuant to Federal Rule of Civil Procedure 37(c)(1), or, alternatively, for clarification regarding the scope of the Court's Order, Dkt. 730.

This Motion is based on the Notice of Motion and Motion, the Memorandum of Points and Authorities, the Declaration of Ryan Hudash and Exhibits thereto, as well as other written or oral argument that Natera may present to the Court.

DATED: October 29, 2024

QUINN EMANUEL URQUHART & SULLIVAN, LLP

By */s/ Derek L. Shaffer*
Derek L. Shaffer
Attorneys for NATERA, INC.,
a Delaware corporation,
Defendant and Counterclaim Plaintiff

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Statutes

Other Authorities

Pursuant to Federal Rule of Civil Procedure 37(c)(1) and *Merchant v. Corizon*, 993 F.3d 733 (9th Cir. 2021), Natera is obligated to, and hereby respectfully does, move for a lesser sanction, or, alternatively, for clarification to the extent that this Court's Order (Dkt. 730) could be read as leaving Guardant free at trial to argue and present evidence contrary to basic, incontestable facts. Natera seeks this relief so that Guardant cannot paint as false what were *truthful* statements by Natera about historic product specificity and the potential for false positives in the Reveal test Guardant marketed and sold. Specifically, Natera hereby respectfully proposes that Guardant's own position as to specificity, removal of the CHIP filter, and the need to reduce false positives be provable through evidence surrounding the COBRA study in the form of:

- [redacted] Ex. 15 (TX-1581, first produced on 6/5/24) at 8.
- [redacted]. Ex. 1 (TX-1667) (7/26/23 letter attaching Guardant Reveal 1.2 Algorithm Update Report), first produced 6/5/24) at 7("[redacted]").
- [redacted] Ex. 2 (TX-1636) (6/22/23 email from Guardant to NRG), first produced 6/5/24) at 1 ("[redacted]").
- [redacted]. Ex. 3 (TX-1663) (5/30/23 FDA submission), first produced 7/9/24) at 21 ("[redacted]").
- **On August 30, 2023, NRG announced to doctors participating in the COBRA trial "that a greater than anticipated number of participants may have been 'false positives', i.e., designated ctDNA+ incorrectly," and that it was closing the study to accrual.** Ex. 4 (TX-1554 (8/30/23 letter)).

Alternatively, the Court might elect to make these basic facts the subject of a straightforward pretrial stipulation. Either way, Guardant should not be free to blind the jury to critical, known facts that bear upon the bottom-line veracity and important patient safety implications of Natera's statements at issue. For purposes of this submission, Natera expressly acknowledges and accepts

the warrant for judicial sanctions,[1] while explaining simply why those sanctions should not go as far as potentially compromising the fundamental fairness of the upcoming trial and raising grave First Amendment concerns.

INTRODUCTION

In assessing sanctions relating to Natera's expert Dr. Hochster, the Court stated it would "turn back the clock" to February 2024 and conduct trial as if it had taken place in March—that is, as if it had granted Guardant's Rule 37 motion to strike the supplemental report of Dr. Hochster and had not permitted the COBRA discovery that proceeded in March-September 2024, with limited exceptions. Dkts. 719; 730 at 2, 16. As part of that sanction, the Court indicated it would exclude "COBRA, any mention of COBRA, and any evidence from or implicating COBRA," Dkt. 730 at 16, including (it appears) evidence that the Court already determined to be relevant and that existed prior to the March 2024 trial date, but had not been produced before the January 2024 supplemental report of Dr. Hochster (such as NRG's public August 30, 2023 "Dear Doctor" letter announcing the COBRA study's closure for excessive false positives and the public January 2024 ASCO-GI presentation discussing those results), as well as documents responsive to Natera's Requests for Production that were withheld by Guardant and came to light during COBRA-related discovery (such as Guardant's 2023 submissions to the FDA regarding [redacted] and Guardant's 2023 correspondence with NRG oncologists explaining [redacted]).

At the heart of the case are competing claims about medical science and patient safety—particularly as to the performance of Guardant's Reveal test and Guardant's claims regarding the same. In 2021, Guardant sued Natera for its alleged comparative performance advertising and for

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[1] Natera's counsel further acknowledges that they should have done better to detect and correct certain misstatements made regarding data and documents relating to Natera's expert, Dr. Hochster, while respectfully reserving rights to challenge any finding to the effect that counsel *knew* the facts as known to Dr. Hochster and knowingly misrepresented those to the Court, or were otherwise acting in bad faith. In all events, Natera's counsel stand by their apology and accept the warrant for an appropriate sanction; this submission is confined to noting that the sanction should remain properly calibrated and not go so far that it potentially skews the jury's understanding of scientific and medical truths.

Natera's White Paper, which explained that CHIP mutations affect specificity in a tumor-naïve assay. The truth of those assertions will be centrally at issue at trial. The excluded evidence shines bright and penetrating light: it establishes that Guardant's assay did ***not*** have 100% specificity as Guardant claimed; that, in stage IIA patient populations, Guardant's assay yielded excessive false positives; and that Guardant fundamentally [redacted]. Per the Court's earlier ruling, "this new evidence is directly admissible to the question of fact regarding whether Reveal had a CHIP filter, and how well the CHIP filter worked irrespective of the Court's previous limits on the COBRA study." Dkt. 653. Likewise, this Court consistently found evidence regarding COBRA and revealed from COBRA-related discovery at least conditionally relevant for trial. *See* Dkts. 493 at 9, 12-13; 653 (Sealed Order regarding Dkt. 632); and 688-4 at 12-22.

The Court's October 23 Order reversing its prior orders raises the specter that Guardant may now proceed to skew the jury's understanding by offering a counterfactual world—one in which basic facts that Guardant knows to be true are nonetheless portrayed as false before the jury. The technical design of Guardant's product, [redacted], translate to known, provable facts. And these basic scientific facts go beyond the FDA process because they reflect the fundamental operation of how Guardant's product worked. Dkt. 719 (citing Dkt. 632-5, Ex. 4). Notably, Guardant's own internal documents about the CHIP filter could also supply direct evidence, but Guardant has continued to withhold those, such that the COBRA-related discovery that was belatedly-produced in June-August 2024 (and some of which came only from third parties) currently supplies the best available evidence on this point.

Ultimately, it is an undisputed fact that NRG closed a major study involving Reveal in August 2023 due to excessive false positives in a stage IIA patient population—precisely the sort of low-prevalence patient population for whom Guardant had promoted its product. The facts that emerged in late 2023 and in subsequent discovery in connection with the COBRA study provide undisputable evidence concerning Guardant's product and its performance in 2021, when Natera's allegedly false and misleading statements were made. Had Guardant continued to fail (inexplicably) to supplement its own discovery responses such that these revelations first came to light post-trial,

then Natera could have sought appropriate relief under Rule 60. Fed. R. Civ. P. 60. As matters stand, however, both parties and the Court already know the truth about these key issues on which the jury's verdict may well turn—prior specificity levels, product design, and proclivity for false positives. The jury, too, should know the truth about these issues, and Guardant should not be permitted to contradict facts long known to it (but not disclosed to Natera and this Court).

It is imperative that the jury be furnished with a full, fair, and balanced factual record because its resulting verdict will carry important consequences not only for these parties but also for larger public policy and understanding. It is a settled fact that patients (particularly stage IIA cancer patients) received apparent false positive results from Guardant's assay; as a result, those patients were subjected to unnecessary, harmful chemotherapy. That tragic state of affairs compelled NRG to close the COBRA study to accrual, lest patients suffer further adverse consequences. Dkt. 447-2, Ex. 7 at 74 ("Dear Doctor" Letter). It would be incompatible with fairness, truth, public policy, and the First Amendment now to let the jury condemn Natera's expression on matters of public concern without regard for the actual facts. Nothing in the Court's sanctions decision justifies following such an extreme, anomalous, and unprecedented course.

Nor does Guardant face any cognizable prejudice from hewing to the basic facts. To the contrary, Guardant was the participant who learned firsthand of the relevant developments in real-time (despite withholding them from Natera and the Court). Although Guardant has yet to explain why it did not supplement its responses to on-point discovery requests, Natera seeks no remedy for that ostensible discovery violation and focuses instead on the merits issues to be tried. It suffices to note that Guardant cannot be prejudiced from having to contend with the known facts, let alone with facts that Guardant learned first, only to withhold them. That is not meant to deny or excuse the fact that Dr. Hochster—one of Natera's expert witnesses and a prominent oncologist—failed to produce emails, misrepresented his search efforts, and provided Natera's counsel erroneous information to report to Judge Kim and this Court (regrettably before Natera's counsel learned it to be erroneous). Those problems are real and the Court has found they warrant appropriate sanctions—but such sanctions should strike a balance by rectifying any prejudice to Guardant without hobbling or skewing the jury's all-important assessment of scientific and medical truths.

It does not follow that the jury should be blinded to key, known facts. Under Ninth Circuit precedent, any sanction should be proportionate to the identified violation and go no further than necessary to rectify it. In this case, it would be a non sequitur to license Guardant to evade facts that were known to it (and the general public, as to the closure of the COBRA study to accrual) no later than January 2024 and would have rightly informed any trial. Instead, lesser sanctions (even above and beyond any monetary sanctions that may be imposed) would prevent the parties from getting into any problematic COBRA details while holding them to stipulated, bottom-line facts such that the jury cannot be misled. As matters stand, Natera has dropped Dr. Hochster as an expert, has accepted the Court's finding of sanctions, and is awaiting briefing on a monetary determination. Natera's instant point is simply and solely that the jury should be alerted to key, provable facts so that it can properly play its role as fact-finder.

BACKGROUND

In March 2017, Guardant applied to NRG to participate in the COBRA study—to test the stage IIA cancer population—[redacted]. Ex. 15 (TX-1581) at 8. This document was not produced until June 5, 2024.

When Guardant released Reveal in early 2021, it claimed the assay had 100% specificity and 100% PPV. Ex. 5 (TX-1356) at 18; Ex. 6 (TX-0576) at 1-2.

On May 3, 2021, Natera issued a technical paper comparing tumor-informed and tumor-naïve approaches for early-stage detection ("White Paper"). Ex. 7 (TX-120) at 1. Without mentioning Guardant Reveal by name, the White Paper stated as follows about the impact of biological noise, such as CHIP, on assay specificity:

> • **Specificity is impacted by biological noise from germline and CHIP mutations.** Without the genomic information for each primary tumor, tumor-naive assays are unable to filter out background biological noise from CHIP or to avoid tracking driver mutations that may be subjected to selection pressure from treatment.

Id. at 2.

On May 27, 2021, Guardant sued Natera, Dkt. 1, alleging the White Paper was "false" because Reveal has bioinformatic software and its specificity is 100% thanks to the "CHIP filter,"

> Reveal can and does filter out CHIP background noise bioinformatically. In fact, data publicly presented in 2018 on a prototype of the Reveal assay showed 100% specificity with incorporation of the CHIP filter.

Dkt. 1, ¶ 32.

In October 2021, the Journal of Clinical Cancer Research published the Parikh study ("Parikh"). Ex. 8 (TX-1). Parikh studied 103 patients from stages I, II, III, and IV of colorectal cancer using Guardant's Reveal assay and referencing COBRA. *Id.* at 3, 7 & n.13. The Parikh study grounds Guardant's advertisements, including the claim that it had 100% specificity.[2] Guardant sued Natera for advertising comparative results of the Parikh and Reinert studies. Dkt. 1.

On March 10, 2022, Natera timely propounded discovery on Guardant. Ex. 9 (Natera's Fourth Set of Requests for Production) at 12. Among Natera's Requests for Production was: "REQUEST FOR PRODUCTION NO. 115: All Documents and Communications concerning FDA regulatory applications for Reveal, including but not limited to, any Investigational Device Exemption (IDE) application(s) for Reveal," to which Guardant objected as untimely. Ex. 10 (Guardant's Responses to Natera's Fourth Set of Requests for Production) at 15. On September 15, 2021, Natera also propounded Interrogatory No. 14, requesting that Guardant "[i]dentify all versions of the genomic and/or epigenomic calling pipeline(s) and/or algorithm(s) ever used as part of Reveal." Ex. 11 (Natera's Second Set of Interrogatories) at 7. Guardant's latest response to Natera's Interrogatory No. 14 was served on April 8, 2022. Dkt. 632-3 at 18-19. Although on May 16, 2022, Judge Kim overruled Guardant's timeliness objection regarding Natera's Fourth Set of Requests for Production (Dkt. 176, Order regarding Dkt. 171), Natera's requests called for supplementation, and Guardant reserved rights to supplement (*see* Ex. 10 at 15; Dkt. 632-3 at 19), Guardant never came forward during the ensuing months to disclose that its interrogatory response was incorrect and productions deficient because Guardant had changed its product, including its [redacted], and had informed the FDA of this

[2] Among Natera's criticisms of Parikh is that she (and unblinded Guardant co-authors) retrospectively removed two false positive patients, resulting in the reported specificity numbers changing from 88% to 100%.

change. No explanation has yet been provided for why Guardant was withholding these materials from Natera and the Court.

On August 30, 2023, the NRG publicly announced that it was closing the COBRA trial to accrual because of excessive false positives:

> We have been informed by our diagnostic partner that a greater than anticipated number of participants may have been 'false positives", i.e., designated ctDNA+ incorrectly. While this was a recognized potential risk of the study, this rate is higher than we had expected. Thus, a subset of COBRA patients randomized to Group 2 who tested positive for ctDNA received chemotherapy based on what is potentially a "false positive" result. The higher-than-expected "false positive" rate resulted in the trial not passing the interim analysis and, as such, the trial will be closed to accrual.

Ex. 4 (TX-1554) at 2. Guardant's fact witness and the author of the only peer-reviewed study on the commercial version of Reveal, Dr. Parikh, publicly tweeted about the closure of the COBRA trial. Ex. 12 (Parikh tweet). [redacted]. Dkt. 704-8.

As of 2024, Guardant's position is that Reveal did not have 100% specificity but was designed for 95% specificity. Indeed, Dr. Parikh, at deposition, conceded the [redacted]. Ex. 13 (Parikh Tr.) at 39:2-8.

In January 2024, Guardant's partner in the clinical study, NRG, published the full interim data and analyzed it at the ASCO-GI conference. Dkt. 447-2 at Ex. 1. There is no dispute that the ASCO-GI conference was the first public presentation of the COBRA study offering full data and analysis. Nor is there any dispute that NRG's publication of the full interim data and its analysis at the ASCO-GI Conference preceded any trial on the claims in this case and would have been known at trial in March 2024, even absent any postponement.

On January 31, 2024 (shortly after the ASCO-GI conference), Natera served a supplemental report from Dr. Hochster relating to the COBRA study, attaching the ASCO-GI abstract and the 13-page ASCO-GI slide presentation. Dkt. 447-2 at Exs. 1 and 2. With his supplemental report, Dr. Hochster also included the August 30, 2023 "Dear Doctor" letter from NRG to participating doctors (including Dr. Hochster) that reported the study's closure to accrual based on excessive false positives from Guardant's Reveal assay. *Id.* at Ex. 7.

After Guardant moved to strike Dr. Hochster's supplemental report, and Natera opposed (Dkts. 447, 452), this Court held hearings on February 15 and February 21, 2024 and entertained supplemental briefing on February 29 and March 1, 2024. Dkts. 482, 484. As of February 2024, Natera was prepared to go to trial in March as scheduled based on the public disclosures regarding COBRA—Dkt. 704-19 (2/15/24 Tr.) at 20:1-5 ("we are prepared to go to trial as scheduled")—albeit without knowing that the COBRA discovery would reveal that [redacted] and that Reveal had much less than 100% specificity. On March 6, 2024, the Court denied Guardant's motion to strike and authorized limited discovery regarding COBRA. Dkt. 493 at 9, 12-13.

On July 9, 2024, NRG produced a Guardant document had submitted to the FDA on May 30, 2023. Dkt. 632-5 at Ex 4. This document is subject to the Court's recent order on exclusion. Dkt. 719 at 2 ("Natera is no longer allowed to use the Guardant/NRG letters regarding Guardant's updates to their CHIP filter in May 2023, as it requires a reference to COBRA and was obtained through COBRA discovery."). Guardant's FDA submission reveals that [redacted] Dkt. 632-5, Ex. 4 at NRG-001261. The upshot of this and other documents from 2023 is that Guardant [redacted] *Id.* [redacted]"). At the Final Pretrial Conference. Guardant's counsel reported that the change to Guardant's assay had been made in spring 2023. Ex. 14 (10/15/24 Tr.) at 59:12-15.

Guardant communicated with NRG throughout 2023, [redacted] Dkt. 632-6 at Ex. 5. The email goes on, "[redacted]." *Id.*

The documents produced during COBRA-related discovery also revealed that Guardant told NRG in July 2023 that Reveal [redacted]." Dkt. 632-8, Ex. 7 at NRG-000124. The report further discloses that Guardant recently [redacted] *Id.* at NRG-000127.

Guardant's Chief Medical Officer, Dr. Eagle (who was deposed during the COBRA-related discovery period), confirmed "[redacted]" and, as a result, Guardant improved "[redacted]." Dkt. 632-9, Ex. 8 (Eagle Tr.) at 153:23-154:3, 154:11-20. Dr. Eagle also testified that Guardant's Reveal assay, when used in real world clinical settings "[redacted]." Dkt. 604-5, Ex. 6 (Eagle Tr.) at 222:17-23.

On September 11, 2024, this Court granted Natera's motion for reconsideration in part, ruling "the Court holds that this new evidence [from COBRA-related discovery] is directly admissible to the question of fact regarding whether Reveal had a CHIP filter, and how well the CHIP filter worked irrespective of the Court's previous limits on the COBRA study." Dkt. 653.

On October 15, 2024, the Court ruled that "sanctions were warranted due to Natera (through its counsel) and Dr. Hochster's deliberate misrepresentations to the Court." Dkt. 719 (Minute Order) at 1. On October 23, 2024, Court issued a written order: "(1) excluding COBRA in its entirety, Dr. Hochster's supplemental report on COBRA, and other discovery flowing from COBRA; and (2) an adverse instruction to be given by the Court regarding Dr. Hochster's credibility."[3] Dkt. 730 at 2.

LEGAL STANDARD

"[A] party facing sanctions . . . bears the burden of showing that a sanction other than exclusion is better suited to the circumstances." *Merchant*, 993 F.3d at 741; *see also* Fed. R. Civ. P. 37(c)(1). According to *Merchant*, "a noncompliant party must avail himself of the opportunity

[3] On October 24, 2024, Natera withdrew Dr. Hochster as an expert witness. Dkt. 735.

to seek a lesser sanction by formally requesting one from the district court." 993 F.3d at 741 (citations and quotations omitted).

Whether awarded pursuant to Rule 37 or the Court's inherent authority, a sanction must be "carefully fashioned to deny [the opposing party] the fruits of its misconduct yet not to interfere" with the right to produce other relevant testimony. *Lewis v. Tel. Emps. Credit Union*, 87 F.3d 1537, 1557 (9th Cir. 1996) (reversing award where sanctions were not tailored to deprive the sanctioned party of information or exhibits wrongly acquired). In determining whether a sanction is proper, courts in the Ninth Circuit consider "1) the public's interest in expeditious resolution of litigation; 2) the court's need to manage its docket; 3) the risk of prejudice to the defendants; 4) the public policy favoring disposition of cases on their merits; 5) the availability of less drastic sanctions." *Wendt v. Host Int'l, Inc.*, 125 F.3d 806, 814 (9th Cir. 1997) (vacating preclusion order); *Scotto v. Gorilla Ladder Co.*, 809 F. App'x 430, 431 (9th Cir. 2020) (no abuse of discretion in denying plaintiffs' motion *in limine* to preclude evidence); *In re High-Tech Employee Antitrust Litigation*, 289 F.R.D. 555, 585 (N.D. Cal. 2013) (denying motion to strike).

While a district court has "broad discretion" under Federal Rule of Evidence 403, it is an abuse of discretion to exclude all evidence related to a particular time period rather than exclude "a few specific pieces of evidence." *Sidibe v. Sutter Health*, 103 F.4th 675, 703 (9th Cir. 2024) (ordering new trial due to blanket exclusion of evidence, much of which was "highly relevant").

No sanction should go so far as compromising fundamental fairness or a jury's ability to ascertain the truth. *Munoz-Santana v. U.S. I.N.S.*, 742 F.2d 561, 564 (9th Cir. 1984) ("A sanction must be just and specifically related to the particular claim at issue in the discovery order."); *Tourgeman v. Collins Fin. Servs., Inc.*, 2012 WL 28289, at *4 (S.D. Cal. Jan. 5, 2012) (denying evidentiary sanctions as "unwarranted and unjust" considering "culpability, prejudice and lesser sanctions"). Moreover, in applying evidentiary rules, the Court should take care not to engender serious constitutional concerns. *United States v. Yida*, 498 F.3d 945, 963 (9th Cir. 2007) (Gould, J., concurring) (district court's interpretation of a federal rule of evidence affirmed in part because the interpretation "avoid[ed] making unnecessary constitutional decisions").

ARGUMENT

Sanctions should stop short of denying the jury its ability to learn basic facts that are essential to understanding Natera's statements at issue and fairly assessing their factual truth or falsity.

A. The Excluded Evidence Is Not Only Probative But Pivotal

The evidence turned up through COBRA-related discovery (but inexplicably withheld by Guardant) serves to debunk Guardant's accusations. Guardant asserted that Natera falsely advertised by noting in a technical paper that tumor-naïve assays have problems with specificity and false positives from CHIP mutations. It is therefore telling that, when COBRA's interim results came in with a "higher-than-expected 'false positive' rate" (Ex. 4 at 2), Guardant told NRG Oncology [redacted] Dkt. 632-6, Ex. 5 at GHI00063336. Indeed, Guardant shared its FDA submission with NRG, which showed that [redacted]. Dkt. 632-5, Ex. 4 at NRG-001261. This evidence disproves aspects of Guardant's claim.

The issue for trial is not a binary question of whether Guardant labeled some part of its software a "CHIP Filter." The issue—as set forth in the Court's Summary Judgment Order—encompasses the "capabilities" of an alleged CHIP filter, as well as "how well it worked." Dkt. 326 at 26. Indeed, as set forth in the Complaint, Guardant's litigation position turns on whether or not the CHIP filter had 100% efficacy or not. The information produced in 2024 directly contradicts Guardant's litigation position regarding its CHIP filter and how well it historically worked in preventing false positives.

In its Complaint (as reaffirmed in its 2024 pretrial statement, Dkt. 699 at 2-3 (referring to Dkt. 362 at 13)), Guardant linked Natera's CHIP filter statements to Guardant's position that studies show Reveal has "100% specificity." Complaint, ¶ 32. That is, Guardant's position has been and remains that Reveal's 100% specificity reflects the test's performance in real-world patients. However, the newly uncovered documents—which should have been produced by Guardant prior to March 2024 and now stand to be excluded—show Reveal does ***not*** have 100% specificity and never did. Lest there be any doubt, Guardant told NRG that [redacted]

[redacted] ("target analytical specificity"), [redacted] Dkt. 632-8, Ex. 7 at NRG-000127. These facts—now effectively undisputed—vindicate Natera's statement and refute Guardant's allegation that Natera was speaking falsely by warning the public that tumor-naïve assays were unable to filter out biological noise. Guardant has conceded that, even with an alleged CHIP filter, Guardant's assay has less than 100% specificity—precisely as Natera set forth in its White Paper.

The centrality of these facts to trial is underscored by the Lanham Act's high standard for proving literal falsity. To prevail under the Lanham Act, Guardant must rely upon unambiguous messages that are susceptible to being literally true or false as a factual matter. *Design Res., Inc. v. Leather Indus. of Am.*, 789 F.3d 495, 501-03 (4th Cir. 2015); *Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Consumer Pharm. Co.*, 290 F.3d 578, 586 (3d Cir. 2002). Here, Natera's literal statements were modest ones, made in technical terms, pointing out merely that tumor-naïve tests "are unable to factor out background biological noise from CHIP or to avoid tracking driver mutations that may be subjected to election pressure from treatment." Ex. 7 (TX-120) at NATERA_350768. Those statements have been fully vindicated by the documents produced by NRG documents as well as Guardant's submission to the FDA. Only by denying established facts might Guardant argue the opposite to a jury.

Likewise, recent factual revelations bear on the truth of Guardant's advertisements that its test has 100% specificity. Guardant has now conceded that its product did ***not*** in fact have 100% specificity. Its witnesses should be no less constrained by real-world facts than Guardant is in acknowledging the limitations of Reveal's prior performance, the changes to its specificity, and the need for a re-design.

B. Ninth Circuit Precedent Calls For Lesser Sanctions

As the Court observed in the first hearing on Guardant's motions for sanctions, "unless the study itself and the results that were obtained were somehow tainted as a result, and the evidence that you were seeking to get and has not been given to you would demonstrate that taint, then I don't, frankly, see a remedy that leads to the total exclusion of the COBRA study." Dkt. 630-2 (7/26/24 Tr.) at 15:20-24. That observation remains correct. Accordingly, the Court asked Guardant

to propose a *lesser* remedy than the total exclusion of COBRA, one proportional to any prejudice. *Id*. at 20:23-21:2; 41:19-42:1. Even though Guardant declined to do so, the Court at the October 15 pretrial conference excluded: "the COBRA study, any material that references it, and forbids the parties from bringing up COBRA at trial." Dkts. 719, Dkt. 730 ("excluding COBRA in its entirety, Dr. Hochster's supplemental report on COBRA, and other discovery flowing from COBRA.").

A lesser sanction is appropriate and sought here. *Merchant.*, 993 F.3d at 742; Fed. R. Civ. P. 37(c)(1). Specifically, Natera seeks a "carefully fashioned" sanction tied to the alleged prejudice. *Lewis*, 87 F.3d at 1558. Guardant's articulated prejudice is that it has spent time and money pursuing discovery from Dr. Hochster regarding his allegedly improper communications with NRG investigators and his access to data regarding the COBRA trial before the results underlying the decision to close the trial to accrual were publicized. That prejudice has been addressed by the de facto exclusion of Dr. Hochster, whom Natera dropped as a witness, and can be further addressed through briefing regarding any appropriate monetary relief compensating Guardant for the reasonable costs it has incurred to the extent the Court finds such relief warranted. But it does not follow that Guardant should be spared from confronting basic facts that are known to all, were uniquely known to Guardant before anyone else, and are indispensable to the jury's fair understanding of the scientific claims on which the trial will turn.

Indeed, Guardant faces no discernible prejudice from the basic facts emerging from the COBRA study, about its own product (as distinct from Dr. Hochster's ensuing expert analyses and opinions). As a temporal matter, these facts publicly emerged in January 2024, before the trial was initially scheduled to commence, irrespective of any postponement (which Guardant sought and obtained for the sake of additional discovery). Thus, rolling back the clock to the day this evidence became public (*i.e.*, before Dr. Hochster opined in light of it) would still leave it in play for the jury's consideration. Moreover, there is every indication that this evidence could have and should have been produced earlier if Guardant had complied with its obligation to supplement its responses to on-point discovery requests. Setting aside any issue of Guardant's ostensible discovery violations, it is inconceivable that Guardant can claim "prejudice" from grappling at trial with the documents and information it had in hand before anyone else. By no means should Guardant now

be afforded a counter-factual windfall at trial, permitting it to argue contrary to the facts that Guardant itself knew, acknowledged, and acted on throughout preceding months.

C. Rule 403 Does Not Afford Separate Basis For Exclusion

This Court's Orders (Dkts. 719, 730) also reference prejudice under Rule 403, but Rule 403 neither addresses misconduct nor supplies a separate basis for the exclusion. Any exclusion under Rule 403 would need to be particularized and tailored to prevent any "unfair prejudice" or other such "danger" that "substantially outweighs" the "probative value" of specified items of evidence—quite different from the wholesale exclusion of smoking-gun evidence. Fed. R. Evid. 403. At most, this Court might exclude any extraneous details of the COBRA study that it sees as threatening to confuse or mislead the jury. Alternatively, the Court might distill the key facts down to a stipulation that would then be available to the jury and for use in possible impeachment. But Guardant faces no discernible prejudice whatsoever from factual recitation of the upshot of the COBRA study—and certainly insufficient prejudice to justify blinding the jury to these critical facts.

Not only was Guardant uniquely privy to these documents and revelations, but [redacted]. Dkt. 704-4. [redacted]. *Compare* Dkt. 704-5, Ex. 4 at GHI00063398 *with* Dkt. 704-6, Ex. 5 at GHI00063471. [redacted]. Dkt. 704-7, Ex. 6. As for Guardant's retained expert, Dr. Parikh, she [redacted]. Dkt. 704-8, Ex 7. Guardant cannot claim that any surprise or unfairness results from the jury learning what Guardant itself has known throughout prior months. On the other side of the scale, the probative value of the evidence in question is enormous, as already noted. Applying Rule 403 in service of a categorical exclusion would be manifestly inappropriate in these circumstances and would imperil the fundamental fairness of the trial and verdict. *Sidibe v. Sutter Health*, 103 F.4th 675, 703 (9th Cir. 2024).

D. Total Exclusion Would Offend Public Policy And The First Amendment

The stakes in this case go well beyond the parties and their commercial interests. Public policy and physician decisions hang in the balance. This case involves cancer patients who are being tested for recurrence of cancer. The lower specificity (95% not 100%) and empirics emerging from testing in low-prevalence populations carry life-or-death implications for patients: in stage IIA patient populations, Guardant's test is expected to lead to "an equal number of false and true positives." Ex. 14 (10/15/2024 Tr.) at 34:23-35:1. Concretely, this means that it was inevitable—to use Guardant's expert's phrasing—that patients received erroneous results from Reveal suggesting their cancer was recurring when it was not, and were therefore subjected to unnecessary chemotherapy. The internal NRG documents from 2023 expressed precisely this concern. Dkt. 582-14 at NRG-N-000162.

This is not a case involving purely commercial speech, which is traditionally subject to reduced (but still meaningful) First Amendment protections. Natera's speech, which is under attack, goes to matters of science and public health, well beyond the commercial marketplace. *Bigelow v. Virginia*, 421 U.S. 809, 825 (1975) (invalidating regulation of advertisement containing factual material of clear public interest). Even if this were a run-of-the-mill Lanham Act case purely about one competitor disparaging another, First Amendment constraints would still stand in the way of punishing or otherwise inhibiting truthful public expression. *See Exeltis USA Inc. v. First Databank, Inc.*, 2017 WL 6539909, at *4 (N.D. Cal. Dec. 21, 2017) (denying motion for preliminary injunction where "[t]o do so would risk erroneously enjoining truthful, protected speech on the basis of an incomplete record"). Regardless of whether Natera's public expression is subject to maximum First Amendment protection (as Natera would urge) or to the First Amendment protections applicable to commercial speech, it cannot occasion liability consistent with the First Amendment so long as it was *factually true*.[4] At the very least, a trial that effectively invites the jury to render a verdict

[4] Although commercial speech jurisprudence leaves open the theoretical prospect that government might restrict truthful, non-misleading commercial speech in furtherance of important ends and with the benefit of narrow tailoring, the Supreme Court has expressed mounting skepticism that government can do so to prevent consumers from accessing accurate factual information. *See Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976); *C.*

indicting scientific claims without regard for known validation would pose grave constitutional concerns of the sort that should be avoided. *See, e,g., King Tuna, Inc. v. Anova Food, Inc.*, 2009 WL 10673202, at *3, n.6 (C.D. Cal. Jan. 28, 2009) ("Suppressing . . . evidence offered to prove allegations that Anova falsely advertises would directly undermine the purpose behind the Lanham Act's proscription of false advertising and would create the false impression that the Court condones an entity's practice of contractually shielding consumers from the truth.").

For these reasons, Natera respectfully submits that sanctions should stop short of potentially undermining public health and the First Amendment. The Court has ready means of compensating Guardant and preventing any remaining prejudice, which would be discrete in this case, and should limit the sanctions accordingly. In no event should it permit the creation of a skewed trial record that suggests Guardant had specificity, design, and capabilities different from what Guardant in fact did, even by Guardant's own account.

CONCLUSION

Natera respectfully requests the Court grant the relief requested herein and avoid imposing sanctions that threaten to impair the jury's ability to understand and apply the actual facts on which the verdict may hinge.

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Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 564 (1980); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 502–03 (1996); *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2658 (2011) ("[T]he fear that people would make bad decisions if given truthful information cannot justify content-based burdens on speech."). The Lanham Act reflects Congress's purpose *only* to protect from harm associated with *false* and *misleading* advertising—very different from truthful scientific information. S.Rep. No. 1333, 79th Cong., 2d Sess., 5 (1946) (Congress intended "to protect the public from imposition by the use of . . . false trade descriptions."). As such, the legality of any ultimate judgment for Guardant would necessarily depend on Natera's speech being properly deemed false.